Strategic Goal: Safe Food

The foods Americans eat will be free from unsafe pesticide residues. Children especially will be protected from the health threats posed by pesticide residues, because they are among the most vulnerable groups in our society.

BACKGROUND AND CONTEXT

The U.S. Environmental Protection Agency (EPA) plays a major role in the lives of all Americans by ensuring that agricultural use of pesticides will not result in unsafe food. EPA accomplishes this by working to protect human health and the environment from risks associated with agricultural pesticide use, while ensuring that exposure from any individual agricultural pesticide use will not, with reasonable certainty, cause harm.

EPA regulates pesticides under two main statutes: the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food and Drug Control Act (FFDCA). FIFRA requires that pesticides be registered (licensed) by EPA before they may be sold or distributed in the United States, and that they perform their intended functions without causing unreasonable adverse effects on people or the environment when used according to EPA-approved label directions.

FFDCA authorizes EPA to set tolerances, or maximum legal limits, for pesticide residues in or on food. Tolerance requirements apply equally to domestically-produced as well as imported food. Any food with residues not covered by a tolerance, or in amounts that exceed an established tolerance, may not be legally marketed in the United States.

Both FIFRA and FFDCA have been amended by the Food Quality Protection Act (FQPA) of 1996, which enhances protection of children and other sensitive sub-populations. Because of EPA's work under these laws, Americans enjoy one of the safest, most abundant, and most affordable food supplies in the world.

Pesticides subject to EPA regulation include insecticides, herbicides, fungicides, rodenticides, disinfectants, plant growth regulators and other substances intended to control pests. The regulations directly affect pesticide producers, formulators, distributors, retailers, commercial pest control firms, farms, farm workers, industrial and governmental users, and all households.

Pesticides are used in agriculture, greenhouses, on lawns, in swimming pools, industrial buildings, households, and in hospitals and food service establishments. Total U.S. pesticide usage in 1995 was about 4.5 billion pounds, and there are about 1.3 million certified pesticide applicators in the U.S. Herbicides are the most widely used pesticides and account for the greatest expenditure and volume. Biopesticides and other non-conventional, or safer, pesticides make up about 20 percent of the total. Agriculture accounts for over 70 percent of all applications.

Through its food safety programs, EPA enhances health and environmental protection in a number of ways, including the following:

- Establishing a single, health-based standard for pesticide residues in food, and eliminating past inconsistencies in the law which treated residues in some processed foods differently from residues in raw and other processed foods.

- Providing for a more complete assessment of potential risks, with special protections for potentially sensitive groups, such as infants and children.

- Ensuring that pesticides are periodically reassessed for consistency with current safety standards and the latest scientific and technological advances.

- Expanding consumers' "right to know" about pesticide risks and benefits.

- Expediting the approval of safer, reduced risk pesticides.

Consumers are at risk for potential adverse effects from pesticide residues ingested either directly or through processed foods. Pesticides also "bioaccumulate" throughout the food chain. A critical step in protecting the public health is to evaluate food use pesticides for potential toxic effects such as birth defects, seizures, cancer, disruption of the endocrine system, changes in fertility, harmful effects to the kidneys or liver, or short term effects such a headaches or disorientation. Ensuring that any residues on food are at acceptable levels is the essence of the Safe Food goal.

EPA's Pesticide Regulation Affects a Cross-Section of the Population:

- 30 major pesticide producers and another 100 smaller producers
- 2,500 formulators
- 29,000 distributors and other establishments
- 40,000 commercial pest control firms
- One million farms
- Several million industry and government users
- About 90 million households

MEANS AND STRATEGY

The Agency works toward a twofold strategy for accomplishing the objectives of the Safe Food goal:

- EPA encourages the introduction of new, safer pesticide ingredients (including new biological agents) within the context of new pest-management practices.

- At the same time, the Agency systematically works toward reducing the use of currently registered pesticides with the highest potential to cause adverse health effects. FIFRA mandates Special Review, reregistration reviews and other risk-management measures available in the registration authority. FQPA mandates additional screening for aggregate exposure, common mechanisms of toxicity and an additional tenfold safety factor to ensure protection of children and infants.

In 2000, the Agency will accelerate the pace of new registrations for pesticides that offer improved prevention or risk reduction qualities compared to those currently on the market. Progressively replacing older, higher-risk pesticides is one of the most effective methods for curtailing adverse impact on health and the ecosystem while preserving food production rates.

Other priorities in 2000 include evaluating existing tolerances for currently registered pesticides to ensure they meet the FQPA health standard and to screen and require testing of certain pesticides and chemicals to evaluate their potential for disrupting endocrine systems in animals or in humans. The emphasis will be on balancing the need for pesticides, and allowing for smooth transitions to safer pesticide alternatives.

EPA uses its FIFRA registration authorities and the FFDCA mechanism in tandem to systematically manage the risks of such exposures by establishing legally permissible food-borne exposure levels, or tolerances. EPA

manages the legal use of pesticides, up to and including the elimination of pesticides that present a danger to human health and the environment. This task involves a comprehensive review of existing pesticide use as stipulated by the reregistration provision, as well as a comprehensive reassessment and update of existing tolerances on a six-year schedule, as required by FQPA.

An additional dimension is the pursuit and incorporation of the latest scientific advances in health-risk assessment practices, ensuring current uses meet the test of a reasonable certainty of no harm, as stipulated by FQPA. This includes the incorporation of new scientific data relating to the effects of endocrine disruption.

Finally, in addition to setting the requirements of continued legal use of agricultural pesticides, EPA works in partnership with USDA, FDA and the states toward the broader effort to prevent the misuse of agricultural pesticides.

More information about EPA's food safety efforts is available on the Office of Pesticides Program's website at http://www.epa.gov/pesticides.

Research

FQPA identifies the need for science to evaluate all potential routes and pathways of human exposure to pesticides and their effects. Research in 2000 will continue the program started in 1998 and will center on such initiatives as assessing the risk of exposures of varying frequency and duration. Research will also compare the effects of pesticide exposure to mixtures of pesticides and other toxics chemicals with exposure to the individual chemicals.

EXTERNAL FACTORS

The ability of the Agency to achieve its strategic goals and objectives depends on several factors over which the Agency has only partial control or little influence. EPA relies heavily on partnerships with states, tribes, local governments and regulated parties to protect the environment and human health.

In addition, EPA assures the safe use of pesticides in coordination with the USDA and FDA, who have responsibility to monitor and control residues and other environmental exposures. EPA also works with these agencies to coordinate with other countries and international organizations with which the United States shares environmental goals. This plan discusses the mechanisms and programs the Agency employs to assure that our partners in environmental protection will have the capacity to conduct the activities needed to achieve the objectives. Much of the success of EPA programs also depends on the voluntary cooperation of the private sector and the public.

Other factors that may delay or prevent the Agency's achievement of some objectives include lawsuits that delay or stop the planned activities of EPA and/or state partners, new or amended legislation and new commitments within the Administration. Economic growth and changes in producer and consumer behavior could also have an influence on the Agency's ability to achieve several of the objectives within the time frame specified.

Large-scale accidental releases, such as large oil spills, or rare catastrophic natural events, could impact EPA's ability to achieve objectives in the short term. In the longer term, new environmental technology as well as unanticipated complexity or magnitude of environmental problems could affect the time frame for achieving many of the goals and

objectives, as could newly identified environmental problems and priorities. In particular, pesticide use is affected by unanticipated outbreaks of pest infestations and/or disease factors, which require EPA to review emergency uses to ensure no unreasonable risks to the environment will result. EPA has no control over requests for various registration actions such as new products, amendments and uses, so its projection of regulatory workload is subject to change.

Resource Summary

(Dollars in Thousands)

	FY 1999 Enacted	FY 2000 Request	FY 2000 Req. v. FY 1999 Enacted
Safe Food	**$67,546.4**	**$78,583.2**	**$11,036.8**
Reduce Agricultural Pesticides Risk	$29,139.0	$30,830.1	$1,691.1
Environmental Program & Management	$26,243.8	$28,725.2	$2,481.4
Science & Technology	$2,895.2	$2,104.9	($790.3)
Reduce Use on Food of Pesticides Not Meeting Standards	$38,407.4	$47,753.1	$9,345.7
Environmental Program & Management	$30,587.9	$39,987.9	$9,400.0
Total Workyears:	702.4	712.2	9.8

Strategic Objective: Reduce Agricultural Pesticides Risk

By 2005, the public health risk from agricultural use of pesticides will be reduced by 50 percent from 1995 levels.

Key Programs

(Dollars in Thousands)

	FY 1999 Enacted	FY 2000 Request
Pesticide Registration	$17,491.6	$19,868.00
Pesticide Reregistration	$4,253.3	$4,227.50
Endocrine Disruptor Screening Program	$1,164.0	$1,167.8
Pesticide Residue Tolerance Reassessments	$976.4	$973.0

Annual Performance Goals and Performance Measures

DECREASE RISK FROM AGRICULTURAL PESTICIDES

In 2000 Decrease adverse risk from agricultural uses from 1995 levels and assure that new pesticides are safe by such actions as registering 6 new chemicals, 1800 amendments, 500 me-toos, 100 new uses, 45 inerts, 375 special registrations, 105 tolerances and 13 reduced risk chemicals/biopesticides.

In 1999 Decrease adverse risk from agricultural pesticides from 1995 levels and assure new pesticides that enter the market are safe for humans and the environment.

Performance Measures:	**FY 1999**	**FY 2000**
Register safer chemicals and biopesticides Registrations	15 Registrations	13
New Chemicals	9 Registrations	6 Registrations
Amendments	2000 Actions	1800 Actions
Me-toos	600 Actions	500 Actions
New Uses	90 Actions	100 Actions
Inerts	45 Actions	45 Actions
Special Registrations	370 Actions	375 Actions
Tolerance Petitions	95 Actions	105 Actions

Baseline: The number of safer pesticides registered (expected to be 46 by the end of 1999) since the passage of the Food Quality Protection Act in 1996. Outputs compared with the previous year's performance.

VERIFICATION AND VALIDATION OF PERFORMANCE MEASURES

The performance measures for this objective are program outputs for the Registration program and are used as an indirect measure of reducing risk. New pesticides undergoing registration using FQPA standards are deemed less risky than most of those registered before FQPA, because the new registrations have to meet a more stringent health standard. Measurement of reduced risk derives from the number of reduced risk pesticides and biopesticides that are registered.

EPA has placed special emphasis on measuring alternatives to organophosphate pesticides that will reduce overall risk. Organophosphate pesticides are widely used but have been shown to have significant health effects. Risk is measured through the health effects, ecosystem effects, and risk assessment screenings that are performed on every pesticide submitted for registration.

Industry is required to provide a wide range of study results to accompany the application for registration. These results are then reviewed by the Agency in a multi-step process which evaluates completeness and appropriateness of the testing. The Agency also reviews the potential interactions and aggregate risk of this pesticide when combined with similar pesticides.

The Agency consults externally with the Science Advisory Panel (SAP) and provides notice and comment on risk assessment results. The screening mechanisms and tools themselves are subject to thorough testing and ongoing improvements through peer review and through the incorporation of the latest scientific findings. Information on pesticide residues is available from various sources, including the Dietary Risk Evaluation System (DRES), the Pesticide Data Program (PDP) and information provided in registrant submissions.

The Agency is also developing a National Pesticide Residue Database (NPRD) which will provide additional data. The performance measures are tracked internally by the Office of Pesticides (OPP) and the information is readily available to the public via several agency databases.

STATUTORY AUTHORITIES

Federal Fungicide, Insecticide and Rodenticide Act (FIFRA)

Federal Food, Drug and Cosmetic Act (FFDCA)

Food Quality Protection Act (FQPA) of 1996

Strategic Objective: Reduce Use on Food of Pesticides Not Meeting Standards

By 2005, use on food of current pesticides that do not meet the new statutory standard of "reasonable certainty of no harm" will be substantially eliminated.

Key Programs

(Dollars in Thousands)

	FY 1999 Enacted	FY 2000 Request
Pesticide Reregistration	$20,718.2	$24,898.1
Endocrine Disruptor Screening Program	$1,417.6	$2,566.2
Pesticide Residue Tolerance Reassessments	$8,564.4	$9,871.0

ANNUAL PERFORMANCE GOALS AND PERFORMANCE MEASURES

REASSESS PESTICIDE TOLERANCES

In 2000 EPA will reassess 20% of the existing 9700 tolerances to ensure that they meet the statutory standard of "reasonable certainty of no harm", achieving a cumulative 53%.

In 1999 Under pesticide reregistration, EPA will reassess 19% of the existing 9,700 tolerances (cumulative 33%) for pesticide food uses to meet the new statutory standard of "reasonable certainty of no harm."

Performance Measures:	**FY 1999**	**FY 2000**
Tolerance Reassessment		1950 Actions
REDs	34 Decisions	20 Decisions
Product Reregistration	750 Actions	750 Actions

Baseline: Baseline is the number of REDs issued, product Reregistrations completed, and the number of tolerances (from a universe of 9700) set in 2000.

VERIFICATION AND VALIDATION OF PERFORMANCE MEASURES

The performance measures for this objective are program outputs for the Reregistration program and are direct measures of reducing the use of pesticides which do not meet the FQPA standard. The performance measures are tracked internally by the Office of Pesticides (OPP). The Pesticide Regulatory Action Tracking System (PRATS) which tracks registration actions, also tracks product reregistration actions. As pre-FQPA tolerances are reassessed, risk from pesticide residues on food will be reduced because the new tolerances must meet the new, more stringent health standard stipulated by FQPA.

The Agency receives information on pesticide residues from a number of sources, such as the Dietary Risk Evaluation System (DRES), the Pesticide Data Program (PDP) and information provided in registrant submissions. The Agency is also developing a National Pesticide Residue Database (NPRD) which will provide additional data.

The DRES is used to conduct acute risk assessment. This system, however, assumes that all crops with registered uses of a pesticide were treated with that same pesticide, and that the crops had residues at the tolerance level. DRES has been refined by incorporating analysis to better adjust for actual use and residue patterns, when appropriate. Science Advisory Panel and stakeholder discussions of appropriate threshold levels are a key part of ongoing verification and validation for this system.

The Pesticide Data program, run by the USDA, has a number of internal verification and validation steps. The USDA interviews individuals regarding everything they ate and drank over the previous twenty-four hours. Additional, non-consecutive days' information is also collected. The data are collected for large numbers of survey participants, scientifically selected so that results can be projected as representative of the U.S. population. USDA survey interviewers are trained to probe for additional information when unusual intakes of various kinds are reported. Additional data checks and validation occurs in the data collection and analysis procedures to ensure that the reported intakes are as accurate as possible.

Through various groups such as the Tolerance Reassessment Advisory Committee (TRAC), the Food Safety Advisory committee (FSAC), the Endocrine Disruptors Screening and Testing Advisory Committee (EDSTAC), the Pesticide Program Dialogue Committee (PPDC), and the State FIFRA Issues Research and Evaluation Group (SFIREG), the Agency is ensuring our review processes under FQPA receive diverse stakeholder input. Additionally, the Agency receives independent scientific peer review from Science Advisory Panel (SAP) and the Science Advisory Board (SAB).

Research

EPA has several strategies to validate and verify performance measures in the area of environmental science and technology research. Because the major output of research is technical information, primarily in the form of reports, software, protocols, etc., key to these strategies is the performance of both peer reviews and quality reviews to ensure that requirements are met.

Peer reviews provide assurance during the pre-planning, planning, and reporting of environmental science and research activities that the work meets peer expectations. Only those science activities that pass agency peer review are addressed. This applies to program-level, project-level, and research outputs. The quality of the peer review activity is monitored by EPA to ensure that peer reviews are performed consistently, according to Agency policy, and that any identified areas of concern

are resolved through discussion or the implementation of corrective action.

The Agency's expanded focus on peer review helps ensure that the performance measures listed here are verified and validated by an external organization. This is accomplished through the use of the Science Advisory Board (SAB) and the Board of Scientific Counselors (BOSC). The BOSC, established under the Federal Advisory Committee Act, provides an added measure of assurance by examining the way the Agency uses peer review, as well as the management of its research and development laboratories.

In 1998, the Agency presented a new Agency-wide quality system in Agency Order 5360.1/chg 1. This system provided policy to ensure that all environmental programs performed by or for the Agency be supported by individual quality systems that comply fully with the American National Standard, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs* (ANSI/ASQC E4-1994).

The order expanded the applicability of quality assurance and quality control to the design, construction, and operation by EPA organizations of environmental technology such as pollution control and abatement systems; treatment, storage, and disposal systems; and remediation systems. This rededication to quality provides the needed management and technical practices to assure that environmental data developed in research and used to support Agency decisions are of adequate quality and usability for their intended purpose.

A quality assurance system is implemented at all levels in the EPA research organization. The Agency-wide quality assurance system is a management system that provides the necessary elements to plan, implement, document, and assess the effectiveness of quality assurance and quality control activities applied to environmental programs conducted by or for EPA. This quality management system provides for identification of environmental programs for which QA/QC is needed, specification of the quality of the data required from environmental programs, and provision of sufficient resources to assure that an adequate level of QA/QC is performed.

Agency measurements are based on the application of standard EPA and ASTM methodology as well as performance-based measurement systems. Non-standard methods are validated at the project level. Internal and external management system assessments report the efficacy of the management system for quality of the data and the final research results. The quality assurance annual report and work plan submitted by each organizational unit provides an accountable mechanism for quality activities. Continuous improvement in the quality system is accomplished through discussion and review of assessment results.

STATUTORY AUTHORITIES

Federal Fungicide, Insecticide and Rodenticide Act (FIFRA)

Federal Food, Drug and Cosmetic Act (FFDCA)

Food Quality Protection Act (FQPA) of 1996

Toxic Substances Control Act (TSCA)